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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,883	11/30/2000	Paul E. Harris	62682/JPW/PT	1468

7590

12/30/2002

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/726,883

Applicant(s)

Harris et al.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 7/30/02, 9/23/02 and 10/22/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 and
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

#### DETAILED ACTION

1. Claims 1-12 are pending and under examination.
2. Applicant's amendment and remarks, filed 10/22/02 are acknowledged. In view of Applicant's amendment of Claims 1 and 2, the previous rejection under the second paragraph of 35 U.S.C. 112 for the recitation of "incubating for a predetermined time period tissue culture" has been withdrawn.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-12 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record as set forth in Paper No. 7, mailed 7/15/02.

Applicant's arguments, filed 10/22/02, have been fully considered but they are not persuasive. Applicant argues that,

"Applicants maintain that the term "dendritic cell culture medium" in claim 7 would be understood by one of ordinary skill in the art in view of the specification of the subject application, to include culturing precursor cells in the presence of cytokines, notably granulocyte-macrophage colony-stimulating factor (GM-CSF) and IL-4 or IL-7 (as well as other maturational cytokines). Additional maturation factors of course may be added to the dendritic cell culture medium, such as recombinant tumor necrosis factor alpha (TNF  $\alpha$ ) [for example, available from R&D Systems, Minneapolis, MN], recombinant soluble CD40L trimeric fusion protein (for example, available from Immunex Corporation), interferon gamma (IFN $\gamma$ ) [for example, available from Actimmune, Intermune Pharmaceuticals, Palo Alto, CA]."

It remains the Examiner's position that the claim is indefinite for the reasons of record. Additionally, it is noted that Applicant's argument in support of the indefinite claim language is itself indefinite in that the argument comprised terms such as "to include". It is clear that no metes and bounds have been defined, thus, the rejection is maintained.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-12 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record as set forth in Paper No. 7, mailed 7/15/02.

Applicant's arguments, filed 10/22/02, have been fully considered but they are not persuasive. Applicant argues that,

"Applicants maintain that it is clear from a reading of the application that loading mononuclear cells into a cell culture container, as provided by the claimed invention, does not require monocytes and monocyte precursors entirely separated from lymphocytes. Indeed, separation of lymphocytes from the adherent cells is a result of applying the claimed method."

It remains the Examiner's position that the specification says what it says "One requirement of blood mononuclear cell (MNC) products suitable for DC culture is collection of a maximum number of monocytes and monocyte precursors with a minimum number of red blood cells, lymphocytes and platelets. This may be accomplished by pheresing donors on an apheresis system (e.g., Spectra, COBE BCT, Lakewood, CO) using a mononuclear cell program." This "requirement" is not part of the claimed invention.

Applicant argues "the specification provides adequate guidance regarding exemplary periods of incubation." It remains the Examiner's position that, as none of Applicant's "exemplary periods of incubation" are recited in the claims, Applicant is arguing an unclaimed limitation and the "reproducible" method of the claims is not enabled.

In regards to the rejection for failing to indicate which group is saved and which group is discarded, the lack of the recitation of any time periods or ranges, and the lack of the

recitation of any specific reagents in the culture medium, Applicant argues,

"Applicants respectfully point out that the claims of a patent application define the boundaries of the subject matter which the applicant claims as applicant's invention, but the claims need not, and indeed usually cannot, set forth all of the details of the subject matter. It is well established in Federal Circuit case law that use of the term "comprising" in a claim, such as in the subject claims, allows the recitation of elements (or steps) in the claim to be open to additional elements (or steps) not specifically mentioned. Further, 35 U.S.C. 112 requires the specification, not the claims, to provide an enabling description."

"In addition, the application provides a number of exemplary, enabling embodiments. For example, a working embodiment, corresponding to FIGS. AD., is described at page 8 line 9 through page 12, line 19."

It remains the Examiner's position that the claims must include the steps essential to delineate the claimed invention. Applicant's arguments regarding steps that could be performed or might be performed, or reagents that could be used or might be used, are insufficient to enable the claimed invention.

Regarding the rejection for lack of failing to recite any ratio, or range of ratios, of microcarrier beads to culture volume, Applicant argues,

"Applicants maintain that the application provides adequate guidance for determining suitable sizes for a cell culture container and microcarrier beads, respectively, without undue experimentation."

It remains the Examiner's position that the use of microcarrier beads comprises a primary element of the invention of the instant claims and as such, some specific description of their use in the claimed method must be recited in the claims to provide an enabled invention.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).

G.R. Ewoldt, Ph.D.  
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December 27, 2002

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